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VALUE IN HEALTH

Impact of Computer-Generated Personalized Goals on Cholesterol Lowering

Claresa S. Levetan, MD,[1] Karen R. Dawn, RN, CDE,[1] James F. Murray, PhD,[2] Jeffrey J. Popma, MD,[3] Robert E. Ratner, MD,[4] David C. Robbins, MD[5]

[1]Department of Internal Medicine, Lankenau Hospital, Wynnewood, PA, USA; [2]Division of Outcomes Research and Biostatistics, Merck, Inc. West Point, PA, USA; [3]Department of Internal Medicine (Cardiology Division), Brigham and Women's Hospital, Boston, MA, USA; [4]MedStar Research Institute, Washington DC, USA; [5]Lilly and Company, Indianapolis, IN, USA

ABSTRACT

Objectives: The National Cholesterol Education Program (NCEP) has enhanced public awareness of the importance of cholesterol in the development of heart disease, yet most patients with cardiovascular disease (CVD) do not know or achieve their low-density lipoprotein cholesterol (LDL-C) goals. This randomized, controlled trial was designed to evaluate the impact of a system that provides uniquely formatted laboratory results to patients with CVD on their changes in LDL-C levels.
Methods: Eighty patients with CVD were randomized to receive standard care or the intervention inclusive of a computer-generated, 11″ × 17″ color poster depicting an individual's LDL-C status and goals along with personalized steps to aid in goal achievement. Cholesterol profiles were obtained at baseline and 6 months after enrollment. Physicians received standard laboratory reports and were blinded to the randomization.
Results: There were no significant differences between patient groups in age, education level, race, baseline cholesterol levels, comorbidities, or percentage of patients in each group who met their NCEP goal at baseline. Patients receiving intervention tools had significant reductions in LDL-C from baseline compared with patients in the control group. Intervention patients who did not meet NCEP goals at baseline had the greatest reduction in LDL-C, with a mean change from baseline of –21.5 mg/dL ($P < 0.001$) whereas standard care patients had no significant change in the LDL-C levels (–4.6 mg/dL, $P = 0.28$). At study close, 73% of intervention patients reported that their posters remained displayed on their refrigerator.
Conclusion: This unique and personalized intervention resulted in the LDL-C lowering benefit among patients with CVD comparable to that of lipid lowering agents.
Keywords: coronary prevention, novel approaches, patient awareness

Introduction

Written goals and objectives lay the foundation for achieving success in most disciplines including business, science and education. Written contracts between health educators and patients have resulted in improved outcomes by shifting the locus of control from the health-care provider to the patient [1,2]. These principles have not typically been incorporated into medical school curricula, nor are physicians exposed to innovative modes of communication that may aid patients in achieving their health goals. For example, persons who know their health goals and believe that these goals are within their control are more likely to have improved outcomes and engage in self-care behaviors including exercise and weight loss programs [1–13].

Because physicians have less time to see more patients, and preventive services are almost nonexistent in most practices, creative solutions are required to address the realities of modern health care. Numerous studies underscore the opportunities missed by physicians for providing preventive cardiovascular counseling and optimizing lipid-lowering medications [14–21]. For example, cardiologists perceived a heightened awareness of the importance of National Cholesterol Education Program (NCEP) guidelines and claimed aggressive cholesterol screening and treatment, yet this was not borne out in their practices [22]. Headrick and colleagues evaluated a variety of educational interventions for physicians, and found that all had a

Address correspondence to: Claresa S. Levetan, 100 Lancaster Avenue, Suite 222 South MOB, Wynnewood, PA 19096, USA. E-mail: levetan@juno.com
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limited impact on improving physician compliance to the guidelines set forth by the NCEP.

Currently, less than 15% of patients with cardiovascular disease (CVD) met their NCEP goals and more than half received no dietary counseling or cholesterol-lowering medication [16]. Avorn and other researchers have valuated how best to deliver messages and feedback to patients regarding their cholesterol goals. Studies have included tailored letters, computerized telephony messages, individualized and group educational sessions, yet, there are no standardized methods for delivering effective messages to patients about their cholesterol status and goals [23–27]. We designed a computer program that produces a unique format for providing patients with their own cholesterol status, goals and steps to meet their goal. We set forth to evaluate whether these customized written goals might facilitate low-density lipoprotein cholesterol (LDL-C) lowering without directly involving the physician among a in high-risk patients with CVD by providing a daily visual reminder for patients and their families.

Patients and Methods

Patients

We receiving approval from The Washington Hospital Center's Institutional Review Board, which included approval of an informed consent form to be signed by all patients to be enrolled in this study. We identified hospitalized patients with documented CVD on the cardiology service at The Washington Hospital Center (a 907-bed, tertiary care teaching hospital) between February 1, 1998 and April 31, 1998. Patients with a history of diabetes were not enrolled to eliminate metabolic parameters that may impact lipids. Patients who could not read were excluded from the study. Patients who had already received a transfusion during their hospital stay or were being evaluated for acute myocardial infarction were excluded to prevent spurious results, and those with an underlying illness, such as malignancy, which was expected to impact their survival over the following 6 months, were excluded from enrollment.

Study Design

All patients were told they were entering an educational study designed to evaluate the impact of cholesterol educational tools on outcomes. Patients who met enrollment criteria and agreed to participate were asked to read and sign informed consent. A nurse obtained baseline demographic data, weight, blood pressure, a list of current medications, and a fasting lipid profile on all patients. A brief patient questionnaire was completed on all participants and included patient report of dietary, exercise and smoking habits.

The questionnaire provided multiple options and participants were asked to select the one best option. Included in the questionnaire was their knowledge of the names for and the difference between the "good" and "bad" cholesterol. At enrollment, all patients who did not know the difference between the LDL-C and high-density lipoprotein cholesterol (HDL-C) were informed. After the initial interview, patients were randomly assigned to receive standard care or the experimental intervention. One hundred cards were randomly assigned to either the intervention or control group and placed in sealed envelopes that were numbered from 1 to 100.

Physicians providing care to both groups received the standard laboratory reporting form with the results of the lipid profile. The results of the lipid profile were also mailed to the patient's physician(s) providing medical care after hospitalization. Laboratory results were available within 1 week of initial enrollment. Baseline LDL-C level was not a study exclusion. Physicians did not receive any of the intervention materials, and were blinded to which of their patients were receiving the active intervention.

Standard care (control). Patients in the control group received usual healthcare advice provided by the hospital, which included hospital discharge materials on cardiovascular health and any additional information provided by their physician. Patients in the standard care group did not receive a personalized report, follow-up phone call or monthly postcards.

Intervention. Each patient in the intervention group received a computer-generated customized report presented as an 11″ × 17″ laminated color poster backed with magnets that graphically depicted their LDL-C, HDL-C, blood pressure, and weight status along with a bulleted list of personalized goals and steps necessary for achievement of the goals (Fig. 1). This was sent by mail immediately after their hospital discharge. Based on the responses to a one-page questionnaire including self-reported diet and exercise habits and the patient's laboratory data, the individual's report was generated from an Microsoft Access97-based decision support system that collected patient information from the enrollment questionnaire and

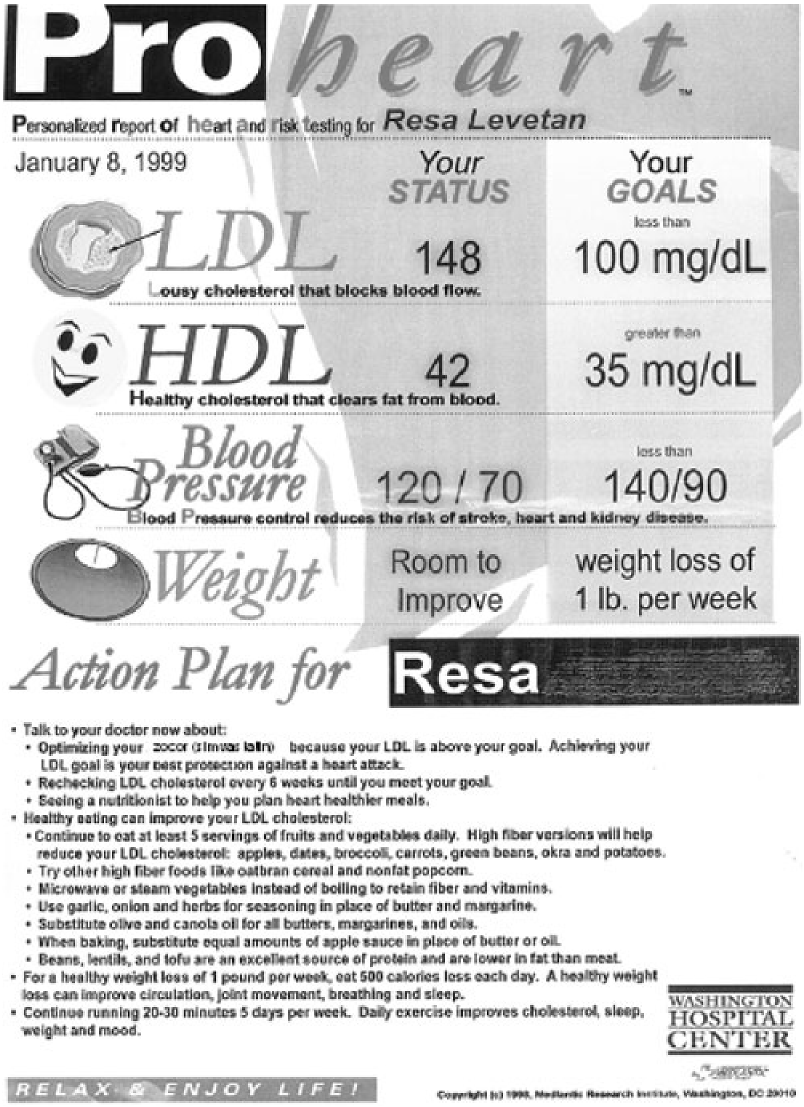

Figure 1 Personalized 11″ × 17″ empowerment poster, laminated and backed with magnets for patients to place on their refrigerator.

matched it against a knowledge base of established diabetes, cardiovascular, nutrition and exercise guidelines.

Patients also received a personalized wallet card that included their baseline lipid and blood pressure status, with room to document subsequent values. One postcard per month was sent to each patient for the duration of the study, which emphasized the relationship between LDL-C and atherosclerosis and provided an action step for LDL-C lowering.

The computer program utilized a relational data decision support system that collected patient information and matched it against a knowledge base of established cardiovascular, nutrition, and exercise guidelines. Greater than 10,000 possible options for each poster's action plan were possible. There was no subjective interpretation from the personal interview, but the questionnaire asked participants to provide the names of family members, pets or friends who exercise, cook or share time with the participant, and these names were included in the personalized reports.

The posters included bulleted points for patients to discuss with their physician. For example, for a patient who was treated with a cholesterol-lowering medication but had not achieved treatment goal, their action plan would include a recommendation to talk to their physician about optimizing their cholesterol-lowering medication. Both the generic and trade names of medications were indicated on the reports.

Recommendations utilized in the computer-generated algorithms were developed from the NCEP, *Healthy People 2000*, the National Institutes of Health Consensus Statement on Physical Activity and Cardiovascular Health and the Departments of Agriculture and Health and Human Services' Dietary Guidelines for Americans [28–32]. The tailored messages were tested among patients for their appropriateness.

After receipt of the personalized tools, intervention patients received one phone call from a health educator to discuss their personalized poster. This phone call was designed to last no more than 10 min and strictly focused on and limited to discussion of the points on the patient's poster. There were no other educational, nutritional, or exercise interventions. Patients were told to discuss issues and questions regarding medication and dosing with their primary physician.

Follow-up

Six months after enrollment, all patients were mailed a follow-up letter and questionnaire. Patients were then contacted to arrange for a follow-up appointment. For patients who wanted their testing carried out in their own physician's office, arrangements were made for delivery and pick-up of specimen kits. At close of the study, all patients and their physicians received a letter with their baseline and follow-up results. Patients in the control group were mailed a personalized poster and wallet card at the completion of the study.

Laboratory Analyses

All cholesterol profiles were performed at Penn Medical Laboratory (Washington, DC). Blood for laboratory measurements was collected by venipuncture after a ~12 h overnight fast. Total cholesterol and HDL-C were measured enzymatically on the Hitachi 717 autoanalyzer using reagents supplied by the Roche Diagnostics Corporation (RDC, Indianapolis, IN). Abel-Kendall analyzed serum, purchased from North-west Lipid Research Laboratory (NWLRL, Seattle, WA), and was used as the calibrator. Controls included those supplied by Roche and NWLRL. The laboratory participates in the NWLRC lipid quality assurance program (Cholesterol Standardization Certification; RELABS). LDL-C was measured directly in fresh plasma using reagents from Sigma Diagnostics (St. Louis, MO).

Statistical Analysis

The power calculation was based on the assumption of achieving a 10% reduction in LDL-C assuming equal variance between the two groups. An estimate of the standard deviation of 0.65 mmol/l (11.7 mg/dL) was used and derived from the Scandinavian Simvastatin Survival Study [33]. The experimental-wise error rate is set at 0.05 (the test-based alpha is 0.025) and the Type II error rate is set at 0.2. An assumption of a dropout rate of 10% per group was based upon descriptions in behavioral interventions [34]. Based on these assumptions, a sample size of 40 per group was projected to reach statistical significance using a Student's *t*-test.

The major outcome variables were LDL-C and total cholesterol. Differences between treatment and control groups at baseline were assessed using two-tailed unpaired *t*-tests. The changes observed within each cohort were evaluated for significant differences between the pre- to postintervention periods using a two-tailed paired *t*-test. The significance of the difference between the treatment and control groups was evaluated by repeated measures of analysis of variance that tested for changes between the two groups from the pre to postintervention periods. A P value of 0.05 was considered statistically significant.

Results

Of the 80 patients enrolled in the study, 35 were randomized to receive the intervention and 45 to the control group. There were no significant differences between the two patient groups in baseline age, education level, race, cholesterol levels, and comorbidities (Table 1). We report the data on the remaining patients in the intervention and the control group who completed the final questionnaire and returned for follow-up cholesterol testing.

After hospital discharge, there were one death in the intervention group and three deaths in the control group, all attributed to CVD. One patient in each group developed a chronic debilitating syndrome (cancer and amyolateral sclerosis); and seven patients in the intervention group and four in the control group declined further participation after hospital discharge. Patients in the intervention group were more likely than the controls to be male.

Patients in both groups had significant prior cardiac histories and did not differ with respect to previous cardiac procedures (Table 1). There were no differences in the percentage of patients in each group who met their NCEP goal, with 34.6% of intervention patients and 35.1% of controls having a baseline LDL-C of <100 mg/dL, $P = 0.21$).

At the 6-month follow-up, there was a significant reduction in LDL-C and total cholesterol from baseline concentrations in patients in the intervention group and no changes in patients in the control group (Table 2). A repeated measures analysis between cohorts adjusting for baseline measures

Table 1 Patient characteristics at baseline

	Control group (n = 37)	Intervention group (n = 26)	*P* value
Age (year, mean ± SD)	59.0 (±15.8)	62.5 (±9.1)	0.26
Male	57%	81%	0.02
Attended college	66.7%	53.8%	0.15
Race			
White	78.4%	84.6%	0.20
African American	18.9%	11.5%	0.38
Other	2.7%	3.9%	0.44
Comorbidities*			
Hypertension	42.3%	55.5%	0.15
Peripheral vascular disease	7.7%	0%	0.04
Previous procedures*			
Catheterizations	2.7 (±2.8)	2.1 (±1.7)	0.15
Coronary bypass surgery	0.75 (1.1)	0.46 (0.7)	0.10
Angioplasty	1.27 (1.4)	1.11 (1.6)	0.34
LDL-C (mg/dL) [mmol/L]	117.8 (±35.9) [6.54]	114.2 (±30.4) [6.34]	0.34
Total cholesterol (mg/dL) [mmol/L]	181.2 (±39.9) [10.07]	187.2 (±29.3) [10.4]	0.25

*Events per patient, mean ± SD.

just failed to achieve a statistically significant difference at the $P = 0.05$ level ($P = 0.059$).

These reductions did achieve significance among patients who had not met their NCEP goals at baseline (Table 3). An evaluation on LDL-C demonstrated a reduction in the intervention group from 131.3 mg/dL to 109.8 mg/dL (–21.5 mg/dL) whereas the change in the control group was from 137.2 mg/dL to 132.6 mg/dL (–4.6 mg/dL). The repeated measures analysis demonstrated a statistically significant difference between the control and intervention groups on LDL-C after controlling for baseline characteristics ($P = 0.034$).

At the 6-month follow-up of the entire cohort, 84.6% of intervention patients and 64.9% of control patients achieved an LDL-C of <130 mg/dL (3.36 mmol/l), a standard now used by the National Committee for Quality Assurance when evaluating lipid control in a population with coronary heart disease [35]. At baseline, fewer than 10% of patients in each group knew the difference between LDL-C ("lousy") and HDL-C ("healthy") cholesterol at baseline, and all patients who did not know difference were told at the time. Based on the follow-up questionnaire, 61% ($P = 0.001$) of intervention patients and 43% ($P = 0.09$) of control patients

Table 2 Cholesterol concentrations at baseline and follow-up, all patients

	Control group (n = 37)				Intervention group (n = 26)			
	Baseline	Follow-up	Change within cohort	*P* value	Baseline	Follow-up	Change within cohort	*P* value
LDL-C, mg/dL (mmol/l) [% change]	117.8 (6.54)	116.7 (6.48)	−1.1 (–0.06) [1.0]	0.43	114.2 (6.33)	101.8 (5.65)	−12.4 (0.69) [10.9]	0.02
Total cholesterol, mg/dL (mmol/l) [% change]	181.2 (10.07)	185.6 (10.31)	+4.4 (0.22) [2.42%]	0.24	187.2 (10.4)	174.7 (9.71)	−12.4 (–0.69) [6.62%]	0.02

Table 3 Cholesterol concentrations at baseline and follow-up, patients who did not meet NCEP goals at baseline

	Control group (n = 24)				Intervention group (n = 17)			
	Baseline	Follow-up	Change within cohort	*P* value	Baseline	Follow-up	Change within cohort	*P* value
LDL-C, mg/dL (mmol/l) [% change]	137.2 (7.62)	132.6 (7.36) [3.35%]	−4.6 (–2.56)	0.28	131.3 (7.29)	109.8 (6.1)	−21.5 (–1.19) [16.4%]	0.001
Total cholesterol, mg/dL (mmol/l) [% change]	202.1 (11.23)	200.5 (11.14)	−1.6 (0.09)	0.43	199.0 (11.06)	175.5 (9.75)	−23.1 (–1.28) [11.6%]	0.001

knew the difference between LDL-C and HDL-C at the end of the study period.

Patients in the intervention group reported they were more likely to talk to their physicians about checking their cholesterol, starting an exercise program, and improving blood pressure management. They were more likely to know their LDL-C and HDL-C goals. All of these follow-up outcomes trended toward, but did not achieve statistical significance. During the study period, intervention patients had fewer cardiac procedures as compared with control patients (7.6% vs. 21.6%), but not at levels that represent statistically meaningful differences that could be attributed to the study intervention. All patients in the intervention group reported that they kept their posters and wallet cards and 73% stated that they placed it on their refrigerator or filing cabinet and their poster remained up at the close of the study.

Discussion

Putting prevention into practice is one of the three major goals of *Healthy People 2000*, the national health promotion and disease prevention objectives of the US Department of Health and Human Services [36]. We designed this intervention based upon the hypothesis that shifting the locus of control from the physician to the patient by providing patients with their own written LDL-C status and goals, could potentially improve outcomes.

We observed a reduction in LDL-C and total cholesterol levels within the intervention group and a more striking and significant improvement among patients with CVD who were not initially at their NCEP goal. We attribute these findings in this pilot study to the written status and goals, which were delivered directly to patients and were a constant visual reminder to patients and their families of their status and the goals.

We learned from the Industrial Revolution that performance and production among assembly line workers were enhanced when individuals were given feedback on their own production rate and knew their goals [36]. These same theories of enhancing task performance by involving patients directly with their cholesterol status and goals, were utilized in this study. Unlike providing generalized knowledge on the subject of cholesterol and heart disease, we allowed patients and their families to have a benchmark of their own personal cholesterol status and their goal. The posters were not thrown away or filed away in a drawer, and 73% of patients kept the poster up on their refrigerator for the duration of the study. Patients commented that they appreciated the simplicity of the reports, as well as the inclusion of the names of pets and family members who accompanied patients with their exercise or activities.

Numerous studies have evaluated physicians' practices and the impact of interventions aimed at the health-care providers, yet there has been limited study of patient interventions that may affect physician practice [37–40]. In this study, physicians were blinded to which patients received intervention tools, thus, we evaluated the impact of an intervention placed solely in the hands of patients.

Enrollment and randomization occurred before the availability of LDL-C results, thus, the inclusion of patients who were at their LDL treatment goal at baseline limited our ability to detect more sizable changes within the entire cohort. Additionally, study completion may have been enhanced had enrollment been limited to those residing locally. All of the patients who declined further participation and follow-up after hospital discharge, resided outside of the immediate vicinity of the hospital. Another limitation was sample size, which was impacted by the funding resources available.

It was the objective of the researchers to help patients feel that good health is achievable, to strengthen their internal locus of control by empowering patients with their own cholesterol status and personalized written goals [41–43]. We embraced the concepts delivered by Dr. James J. Putnam in 1899, that "medicine is not only the disease, but also the man [44]." The investigators believe that the greatest impact resulted from patients seeing their own cholesterol status and goal, because few even knew the difference between LDL-C and HDL-C at baseline and none knew their individual LDL-C levels.

Evaluating health-care outcomes is vital to effectively close the gap between scientific advances and the practice of medicine. Although we demonstrated that this intervention could potentially have a profound impact on short-term LDL-C outcomes, the small sample size and selected population with CVD limits the generalization of these results. Further study is necessary to evaluate the long-term benefits and economic impact of tools such as the ones we designed, not only among patients with CVD, but also among patients at risk for CVD who have not had a cardiac event.

Our data demonstrated that when patients with CVD were given a personalized wall poster depicting their cholesterol status and goals, their cholesterol levels declined. The impact of having their individual levels and goals in front of them was more effective than any known behavioral intervention in lowering cholesterol in heart disease patients. Further study is necessary to determine the long-term implications of such interventions on cholesterol levels and outcomes.

The software algorithm utilizes laboratory data and patient data derived from a short questionnaire that can be self-administered. The investigators have developed a system to make these tools available to physician practices and managed care populations with the cost of this intervention approximating the cost of one dosage of a lipid-lowering agent.

As we develop a strategic health plan for the 21st century, the critical research that identifies the genetic, physiological, and environmental determinants of disease must be accompanied by outcomes-based research that evaluates how the scientific advances can best be translated into cost-effective and practical steps that patients can take to improve their health. Not only must we ensure that patients receive optimal medical care for an illness when it strikes, but also ensure that patients understand the important role that they themselves play in setting and achieving their own health goals.

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